

EXHIBIT 1

Expert Report of James Geldhof
Based Upon Review as of August 3, 2020

I. Experience and Training

I graduated in 1972 from Eastern Michigan University with a Bachelor of Business Administration. I was hired by the Drug Enforcement Administration in 1972 and completed Basic Diversion Investigator School. I spent more than 40 years employed by the DEA and retired from there in 2016.

From June 1972 through August of 1974, I was a DEA Diversion Investigator out of Detroit, Michigan during which I conducted a full range of investigations of DEA registrants. I was responsible as lead investigator for the prosecution of the Vice President of a local pharmaceutical company and the subsequent revocation of the company's DEA license. I also met with and spoke to various pharmaceutical companies regarding their responsibilities under the Controlled Substances Act.

Effective August of 1974, I was promoted to DEA Staff Assistant in Washington, DC where I was responsible for coordinating investigative efforts over six divisions. My responsibilities included personnel support, policy interpretations, funding and liaison with other components of DEA Headquarters, and liaison between field and headquarters within the Diversion Program. I prepared the Diversion Control Budget for the entire Diversion Program. I initiated division evaluation programs to assist in staffing personnel. While not on staff, I also taught classes at the DEA's Training Academy on a number of different topics.

In June 1978, I became the DEA Diversion Group Supervisor in New York, New York office. I moved to the Newark, New Jersey office in July 1979 where I stayed until I moved back to the Detroit, Michigan office in July 1986. As a DEA Diversion Group Supervisor, I supervised the Diversion Groups in the cities I identified. My Groups were tasked with investigations of regulatory, criminal, civil and administrative cases aimed at preventing diversion of controlled substances. Under my supervision, my Groups' investigations resulted in regulatory, criminal, civil and administrative actions taken against those responsible for violating the laws and regulations governing the manufacture, distribution, prescribing and dispensing of controlled substances.

In July 2005, I became Acting DEA Diversion Program Manager and was made permanent Diversion Program Manager in October 2005 in the Detroit, Michigan office. As Diversion Program Manager, I was responsible for oversight of Diversion Groups throughout Michigan, Ohio and Kentucky. I was responsible for oversight of investigations, personnel, budget control, and I was a liaison to a number of other state and federal agencies. Among the many enforcement actions, I participated in were Harvard Drug, KeySource Pharmaceutical, Masters Pharmaceutical, McKesson, Miami-Luken and Mallinckrodt. I also represented the DEA in any number of meetings with law enforcement and professional and community groups. I remained in this position until I retired from the DEA in January 2016.

Throughout my tenure at the DEA, I participated in and completed a number of training programs, conferences and seminars addressing the laws and regulations and the enforcement of the laws and regulations governing the manufacture, distribution, dispensing and prescribing of

controlled substances. I also qualified for and obtained Top Secret Security Clearance. Additionally, I received numerous awards and commendations for my performance throughout the years.

Since my retirement in 2016, I have used my knowledge, experience and training in a number of consulting roles. I have been hired by members of the pharmaceutical and health care industries to evaluate and assess their compliance with the laws and regulations governing the handling of controlled substances under the Controlled Substances Act. I have testified by deposition once in the last four years as an expert in *Staubus et al. v Purdue Pharma, L.P.*, et al., Case No. C41916, Circuit Court for Sullivan County, Tennessee. I am unaware of any time that my opinions were limited or stricken by a court.

I have been retained as a consultant in this matter and intend to provide my opinions regarding the history of the laws and regulations governing the pharmaceutical industry and the enforcement by the DEA of the laws and regulations as they apply to distributors. I am paid \$300.00 per hour to review documents, communicate with counsel, and for any time spent testifying whether in deposition or before the court.

Based upon my extensive training, knowledge and experience, I am familiar with the legal and regulatory framework that exists governing the manufacture, dispensing, prescribing and distribution of controlled substances. I am also familiar with the enforcement mechanisms available to the State and Federal agencies to enforce the governing laws and regulations.

II. Laws and Regulations

In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act.¹ Title II of the Act contains the enforcement provisions and is known as The Controlled Substances Act (“CSA”). 21 USC ss 801-971. The Drug Enforcement Administration (“DEA”) was created by President Nixon in 1973 as part of a reorganization of the many agencies involved at the time in the enforcement of the laws and regulations governing controlled substances. The DEA was placed under the authority of the Department of Justice.² The reason for the CSA is stated in the Act itself: “The illegal importation, manufacture, distribution and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American People.” 28 USC s 801(2) (2006). Each distributor owes a duty to ***maintain effective control*** against diversion of prescription opiates into the illicit market.³

The Controlled Substances Act and the regulations that implement the CSA create restrictions on the manufacturing, distributing, prescribing and dispensing of certain substances and chemicals. There are five schedules into which the regulated drugs, substances and chemicals

¹ 84 STAT Public Law 91-513 (Oct. 27, 1970).

² <https://www.dea.gov/sites/default/files/2018-07/Early%20Years%20p%2012-29%20%281%29.pdf>

³ 21 U.S.C. § 823(b)(1) (1970) (*emphasis added*.)